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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
HUNTSVILLE DIVISION

JANICE FLANNAGAN and JEFFREY FLANNAGAN Plaintiffs, vs. AMERICAN MEDICAL SYSTEMS, INC., AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., ENDO PHARMACEUTICALS, INC., ENDO PHARMACEUTICALS HOLDINGS, INC., ENDO HEALTH SOLUTIONS, INC., COOK BIOTECH, INC., COOK MEDICAL, INC., COOK, INC., and COOK GROUP, INC. Defendants.	)	COMPLAINT AND JURY DEMAND Civil Action No.

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiffs, JANICE FLANNAGAN AND JEFFREY FLANNAGAN, bring this Complaint against Defendants American Medical Systems, Inc., American Medical Systems Holdings, Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc. and Endo Health Solutions Inc. (hereinafter jointly referred to as AMS) as well as Cook Biotech, Inc., Cook Medical, Inc., Cook, Inc. and Cook Group, Inc. (hereinafter jointly referred to as Cook) as follows:

NATURE OF CASE

1. This is an action for damages suffered by JANICE FLANNAGAN AND JEFFREY FLANNAGAN ("Plaintiff"), as a direct and proximate result of Cook and AMS's wrongful conduct in connection with the development, design, manufacture, marketing,

distribution and selling of Cook and AMS's Pelvic Mesh Products[1] inserted in Plaintiff JANICE FLANNAGAN'S body to treat medical conditions, primarily pelvic organ prolapse and/or stress urinary incontinence.

PARTIES

2. Plaintiffs are citizens of the State of Alabama, County of Limestone, and the City of Elkmont.

3. Defendant American Medical Systems, Inc. is a for profit corporation organized and existing under the laws of Delaware with its corporate headquarters in Minnesota. American Medical Systems, Inc. may be served through its registered agent at American Medical Systems, Inc., 3070 Orchard Drive, San Jose, California 95134; its president Anthony P. Bihl, III at 10700 Bren Road West, Minnetonka, Minnesota 55343; or the Delaware Registered Agent for Service, Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Defendant American Medical Systems, Inc. is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc. Defendant American Medical Systems, Inc. is a wholly owned subsidiary of defendant Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc. and Endo Health Solutions Inc. At all times material hereto, American Medical Systems, Inc. did business in Alabama

4. Defendant American Medical Systems Holdings, Inc. (AMS Holdings) is a Delaware corporation and may be served pursuant to 10 Del. C. Section 3111 by serving its registered agent, Corporation Trust Company at 1209 N. Orange Street, Wilmington, Delaware

[1] The term Pelvic Mesh Products includes Cook and AMS's mesh, hammock and sling products used to treat pelvic organ prolapse and/or stress urinary incontinence. The term Pelvic Mesh Products also specifically includes the AMS products implanted into Plaintiff, which include AMS Perigee System and Monarc Sling, and the Cook products implanted into Plaintiff, which include the Surgisis Biodesign Tension-Free Urethral Sling (hereinafter "Products").

19801 and is the parent of wholly-owned subsidiary American Medical Systems, Inc. At all times material hereto, American Medical Systems Holdings, Inc. did business in Alabama

5. Defendant Endo Pharmaceutical, Inc. (Endo) is a Pennsylvania corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. At all times material hereto, Endo Pharmaceutical, Inc. did business in Alabama

6. Defendant Endo Pharmaceuticals Holdings, Inc. (Endo Holdings) is a for profit corporation organized and existing under the laws of Delaware with its corporate headquarters in Pennsylvania. On June 20, 2011, AMS became a wholly owned subsidiary of Endo Pharmaceuticals Holdings, Inc. Endo Pharmaceuticals Holdings, Inc. may be served through its registered agent at Endo Pharmaceuticals Holdings, Inc. 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317; or the Delaware Registered Agent for Service, Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. On May 23, 2012, Endo Holdings changed its name to Endo Health Solutions, Inc. At all times material hereto, Endo Pharmaceuticals Holdings, Inc. did business in Alabama

7. Defendant Endo Health Solutions, Inc. (Endo Health Solutions) is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 and is the parent of American Medical Systems, Inc. and AMS Holdings. At all times material hereto, Endo Health Solutions, Inc. did business in Alabama

8. Defendant Endo Health Solutions has aggregated four operating businesses into one enterprise including American Medical Systems, Inc. and AMS Holdings.

9. At all relevant times, defendant Endo merged with American Medical Systems, Inc. and as part of that acquisition, purchased and assumed all liability relating to legal claims arising from the implantation of defective synthetic pelvic mesh systems.

10. Defendant Cook Biotech, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906. Defendant Cook Biotech Inc. alleges as follows: it was created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The company conducts research, development and manufacturing operations in a state-of-the-art facility. Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials. In cooperation with university researchers, Cook Biotech has developed a line of products that can remodel native tissues using a biomaterial made from porcine small intestinal submucosa (SIS). Several FDA-cleared products using this technology to dress wounds or to surgically repair soft tissues are currently available from Cook and its distributors. Numerous potential medical applications for products made from SIS and other nature tissues are under development. *See http*://www.cookmedical.com/profile.do?id=profile biotech. All acts and omissions of Cook Biotech, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Biotech, Inc. did business in Alabama.

11. Defendant Cook Medical, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195. Defendant Cook Medical Incorporated alleges as follows: it was established to offer a synchronized service for the efficient purchase and distribution of all Cook medical devices. With particular focus on lowering supply chain costs, the company coordinates price file access, purchase orders, ship points and accounts payable. All acts and omissions of Cook Medical, Inc. as described herein were done by its agents, servants, employees and/or owners, acting

in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Medical, Inc. did business in Alabama.

12. Defendant Cook, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Incorporated alleges as follows: it is also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts. All acts and omissions of Cook, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook, Inc. did business in Alabama.

13. Defendant Cook Group, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404-9120. Defendant Cook Group Incorporated alleges as follows: it was founded to help manage financial, legal and regulatory issues that emerged as the Cook companies expanded in the United States and abroad. All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Group, Inc. did business in Alabama.

14. Defendants Cook Biotech, Inc. and Cook Medical, Inc. are subsidiaries of Cook, Inc. Cook Group, Inc. is the parent company and did the following through its subsidiaries named herein: designed; secured clearance for sale; manufactured; labeled; marketed; distributed; sold; benefited financially from the sale; and placed into the stream of

commerce the products implanted in Plaintiff JANICE FLANNAGAN. The Cook Defendants, as such, are individually, jointly and severally liable to Plaintiffs.

15. Upon information and belief, and upon review of the Cook Defendants' own combined website, Plaintiffs assert that the following Cook Defendants' participated in placing the product implanted in Plaintiff JANICE FLANNAGAN into the stream of commerce causing her injuries: Cook Group, Inc. is the parent and nerve center of the Cook operations which, through its subsidiaries designed, tested, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Incorporated participated in the development of the subject medical device; Defendant Cook Biotech, Inc. developed, with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; and Defendant Cook Medical, Inc. was the central and key agent in the distribution of Plaintiff's medical device.

16. All acts and omissions of each Cook Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

17. The Cook Defendants share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Cook".

JURISDICTION AND VENUE

18. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants American Medical Systems, Inc., AMS Holdings, Endo, Endo Holdings, Endo Health Solutions, Cook Biotech, Inc., Cook Medical, Inc., Cook, Inc. and Cook Group, Inc.

(hereinafter Cook and AMS shall be jointly referred to as Defendants) are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

19. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as this is the judicial district where a substantial number of the events, actions or omissions giving rise to Plaintiffs' claims occurred. At all times material hereto, AMS and Cook were for profit corporations authorized to and doing substantial business in this district.

20. At all times material hereto, Cook developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products at issue in this matter. By said activities, Cook's Pelvic Mesh Products are placed into the stream of commerce throughout the United States, including within the State of Alabama.

21. At all times material hereto, AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products at issue in this matter. By said activities, AMS' Pelvic Mesh Products are placed into the stream of commerce throughout the United States, including within the State of Alabama.

22. At all times material to this action, Cook and AMS both designed, patented, manufactured, labeled, marketed, sold and distributed a line of pelvic mesh products. The products by Cook and the products by AMS were both designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. The Cook and AMS products share common design elements and common defects. Moreover, Cook's product at issue in this case was cleared for sale in the U.S. after Cook made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and

Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy. Likewise, AMS' product at issue in this case was cleared for sale in the U.S. after AMS made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

23. Defendants are subject to personal jurisdiction in this district as Defendants systematically and continually conduct business in this district, and both Cook and AMS conduct business throughout the United States, including in Alabama.

FACTUAL ALLEGATIONS
PELVIC ORGAN PROLAPSE PRODUCTS BACKGROUND

24. AMS develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution Pelvic Mesh Product medical devices for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

25. AMS' and Cook's Pelvic Mesh Products were derived from polypropylene mesh hernia products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

26. AMS' Pelvic Mesh Product at issue in this litigation contains polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the female pelvic is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with AMS' Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

27. AMS' biologic mesh products, made mainly of collagen, and Cook's biologic products, Surgisis Biodesign Tension-Free Urethral Sling, are likewise biologically incompatible with human tissue and promote a negative immune response in a large subset of the population implanted with AMS and Cook's biologic mesh products. These biologic products cause hyper-inflammatory response leading to problems including chronic pain and fibrotic reaction. AMS and Cook's biologic products disintegrate after implantation in the female pelvic. The AMS and Cook biologic products cause adverse tissue reactions, and are causally related to infection, as the biologic material is a foreign material derived from animal tissue. Animal tissue is harsh upon the female pelvic tissue. It hardens in the body. When AMS and Cook's mesh is inserted in the female body according to the manufacturer's instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

28. Defendants AMS and Cook both develop, design, manufacture, label, package, distribute, market, supply, advertise, sell and otherwise engage in all activities that are part and parcel of the sale and distribution medical devices, including medical devices implanted to treat certain women, like Plaintiff, for pelvic organ prolapse and stress urinary incontinence (hereinafter "Products"). The Pelvic Mesh Products specifically implanted into Plaintiff JANICE FLANNAGAN as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

29. As to Cook, in or about 1999, Cook began to market and sell products for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

30. Specifically, Cook Group, Incorporated, by and through its subsidiary, Cook Biotech, Inc., sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of stress urinary incontinence: Surgisis Biodesign Urethral Sling on September 23, 1999 and Surgisis Biodesign Tension-Free Urethral Sling on April 9, 2002. Cook Biotech, Inc. sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of pelvic floor repair: Surgisis Biodesign Anterior Pelvic Floor Graft; Surgisis Biodesign Posterior Pelvic Floor Graft; and Surgisis Biodesign Vaginal Erosion Repair Graft on September 23, 1999.

31. Cook's products were derived largely from hernia mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

32. Cook's Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by Cook, at all times relevant herein.

33. Cook makes the following assertions regarding its products:

> Surgisis Biodesign is not a new- graft or mesh, but a whole new category in the evolution of tissue repair. A breakthrough technology, it incorporates the best attributes of a biologic graft—**resistant to infection and complete remodeling**—with the added benefits of moderate price, ease of use and widespread availability. Surgisis Biodesign offers you a new level of assurance and, most important, contributes to an improved quality of life for your patient.

See http://www.cookmedical.com/bioNew/bio overview.html.

34. Cook further asserts the following about their Biodesign products: "And unlike synthetic mesh, **nothing is left permanently in the body to cause problems down the road**." *See* http://www.cookbiodesign.com/for-patients/conditions/fistula/faqs.

35. On August 20, 2011, Cook issued a communication to the FDA in advance of the September 2011 Advisory Committee Hearings regarding the investigation into the risks associated with mesh for stress urinary incontinence and pelvic floor repair and/or pelvic floor prolapse. In its communication, Cook assert regarding its non-cross linked biologic matrix that: "**[a]ny inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain**."

36. Contrary to Cook's assertions that its products are resistant to infection; result in complete remodeling, are limited in inflammatory response to area where synthetic sutures are/were utilized during surgery and will not cause any problem down the road, the following non-inclusive literature suggests otherwise:

> In November of 2005, results from a study were published in the International Journal of Obstetrics & Gynecology relating to the comparison of the host response, architectural integration and tensile strength of polypropylene to porcine small intestine submucosa-derived implants including Defendants SIS products. Implants from the SIS group showed a short term increase in thickness in the first 14 days. **Formation of adhesions was significantly more extensive in the SIS group at 90 days. Tensile strength increased over time in both groups but was significantly lower in the SIS group. Implants in the SIS group showed inflammatory response.**

Konstantinovic ML., Lagae P., Zheng F., Verbeken EK., De Ridder D., Deprest JA. (2005). Comparison of Host Response to Polypropylene and Non-Cross-Linked Porcine Small Intestine Serosal-Derived Collagen Implants in a Rat Model. *BJOG: An International Journal of Obstetrics & Gynecology*, 112(11),1554-1560.

> In October of 2008, results from a study were published in the Archives of Gastroenterology relating to the comparison of the repair of induced abdominal wall defects with Defendants' Surgisis mesh and Covidien, Inc.'s Parietex. Both meshes induced skin erosions. There were peritoneal adhesions to the surface of both types of meshes after 30 and 60 days. **Meshes' shrinking correspond to 1/3 of the original size and Parietex caused less inflammatory process at the histologic evaluation**.

Baroncello JB., Czeczko NG., Malafaia O., Ribas-Filho JM., Nassif PA., Dietz AU. (2008). The Repair of Abdominal Defects in Rabbits with Parietex and Surgisis Meshes Abdominal wall. *Arquivos de Gastroenterologia*, 45(4), 323-9.

> In November of 2008, results from a study were published in Urology relating to reports of intense local inflammatory reactions in patients undergoing pubovaginal sling or tape using a small intestinal submucosa graft. **After implantation of 16 standard pubovaginal sling or tension-free tape procedures for stress urinary incontinence, using the Cook 4-ply Stratasis or 8-ply Stratasis-TF system, 5 (31.3%) had intense suprapubic pain after surgery. One patient had induration of the mons pubis that required surgical drainage. One patient had vaginal inflammation, with expulsion of graft material. Other patients had intense rectus sheath inflammation, as confirmed on computed tomography. This study confirmed previous case reports of inflammatory complications of small intestinal submucosa leading to that institution's cessation of use of Defendants' products**.

John TT., Aggarwal N., Singla AK., Santucci RA. (2008). Intense Inflammatory Reaction with Porcine Small Intestine Submucosa Pubovaginal Sling or Tape for Stress Urinary Incontinence. *Urology*, 72(5), 1036-9.

> In January of 2009, results from a study were published in the Journal of Biomedical Materials Research Part B relating to the evaluation of Defendants' Surgisis Gold to other materials including C.R. Bard, Inc.'s Permacol; Ethicon's Prolene mesh and Life Cell's Alloderm in the context of human mesothelial cells. **The results of the study indicate that Surgisis Gold was inferior in aiding in the growth and fibrinolytic activity of human mesothelial cells than other products.**

Wilshaw SP., Burke D., Fisher J., Ingham E. (2009). Investigation of the Antiadhesive Properties of Human Mesothelial Cells Cultured in Vitro on Implantable Surgical Materials. *Journal of Biomedical Materials Research Part D: Applied Biomaterials*, 88(1), 49-60.

> In October of 2011, results from a study were published in the Archives of Gastroenterology relating to the comparison of different biologic materials regarding relative implant integration, shrinkage, and foreign body reaction. Relating to **Defendants' Surgisis, the integration of its product was insufficient and could detached easily from the underlying tissue; the penetration of fibroblasts and vessels was limited; foreign body reaction was pronounced, leading to persistent granulomatous inflammation; and shrinkage was excessive in comparison to**

> **all other products. Other products yielded sufficient anti-adhesion and elicited no foreign body reaction.**

Petter-Puchner AH.**,** Fortelny RH., Silic K, Brand J., Gruber-Blum S., Redl H. (2011). Biologic Hernia Implants in Experimental Intraperitoneal Onlay Mesh Plasty Repair: The Impact of Proprietary Collagen Processing Methods and Fibrin Sealant Application on Tissue Integration. *Surg Endosc*, 25(10), 3245-52.

> In February of 2012, results from a study were published in Hernia relating to the comparison of different biologic meshes including Defendants' Surgisis Gold regarding the relative performance and efficacy as between two non-crosslinked meshes and two crosslinked prostheses. **Major complications seen with Defendants' product included: that it appeared to be wrinkled and folded by excessive shrinkage, eliciting severe adhesions and a pronounced local inflammation, characterized by foreign body giant cells. The multilayer design was preserved but disintegrated by transversal movement of layers against each other**.

De Castro Brás LE., Shurey, S., Sibbons, PD. (2012). Evaluation of Crosslinked and Non-Crosslinked Biologic Prostheses for Abdominal Hernia Repair. *Hernia,* 16(1), 77-89.

> In September of 2012, results from a study were published in Biomaterials relating to the clinical performance of biomaterials in the context of comparing leukocyte activation by commercially available biologic surgical materials and define the extent manufacturing variables influence down-stream response. The data demonstrated **Defendants' Surgisis Biodesign which was implanted in Plaintiff showed excessive leukocyte activation and was significantly more pro-inflammatory as compared to the other products analyzed. High degrees of leukocyte activation lead to poor material/patient compliance, accelerated degeneration and graft rejection**.

Bryan N., Ashwin H., Smart N., Bayon Y., Scarborough N., Hunt JA. (2012). The Innate Oxygen Dependant Immune Pathway as a Sensitive Parameter to Predict the Performance of Biological Graft Materials. *Biomaterials*, 33(27), 6380-92.

37. Plaintiff JANICE FLANNAGAN was implanted with AMS' and Cook's Pelvic Mesh Products developed, designed, manufactured, marketed, packaged, labeled, distributed, supplied, advertised, sold and placed in the stream of commerce by Defendants. Due to defective design, defective manufacturing, defective marketing, failure to warn and negligence

by Defendants AMS and Cook, the Products have caused Plaintiff JANICE FLANNAGAN severe and permanent bodily injuries and significant mental and physical pain and suffering, as well as economic losses.

38. Defendants' Pelvic Mesh Products, including the Pelvic Mesh Products specifically used for Plaintiff JANICE FLANNAGAN, have been and continue to be marketed to the medical community and to patients as safe, effective, reliable medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. Defendants market the Pelvic Mesh Products, including the Products specifically used for Plaintiff JANICE FLANNAGAN, as safer and more effective when compared to 1) the traditional products and procedures for treatment of pelvic organ prolapse and stress urinary incontinence and 2) other competing pelvic mesh and sling products.

39. Defendants made public statements in the form of written product descriptions, product labels, promotional materials, marketing materials and other materials that asserted that implanting the Pelvic Mesh Products in patients was safe and would not cause harm to patients, like Plaintiff JANICE FLANNAGAN. Defendants have also marketed and sold its Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to healthcare providers at medical conferences, hospitals, private offices and include the provision of valuable consideration and benefits to healthcare providers. Also utilized are documents, brochures, websites, telephone information lines, and training offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Products.

40. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to Plaintiff JANICE FLANNAGAN. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b. The mesh material harbors infections that adversely affect human tissues and patient heath.

c. The Pelvic Mesh Products migrate from the location of their implantation, adversely affecting tissues and patient health.

d. The mesh material abrades tissues adversely affecting patient health.

e. The Pelvic Mesh Products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the Pelvic Mesh Products regularly cause significant injury to patients such that the Pelvic Mesh Products must be removed, resulting in additional surgery.

g. The Pelvic Mesh Products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.

h. The Pelvic Mesh Products are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the female pelvis.

i. The Pelvic Mesh Products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.

41. Because of their numerous defects, the Pelvic Mesh Products create an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction,

infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to the woman's intimate partner.

42. Defendants made, participated in and/or contributed to filings with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for Defendants' Pelvic Mesh Products.

43. Upon information and belief, Defendants sent to the FDA a 510(k) submission for its Pelvic Mesh Products.

44. Upon information and belief, Defendants were in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of product warnings and related information with respect to its Pelvic Mesh Products.

45. Defendants have consistently underreported and withheld information about the propensity of its Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

46. Defendants have known and continue to know that its disclosures to the FDA were and are incomplete and misleading; and that its Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, healthcare providers, or the patients. As a result, Defendants actively and intentionally misled and continue to mislead the public, including the medical community, healthcare providers and patients, into believing that its Pelvic Mesh Products were and are safe and effective, and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Pelvic Mesh Products and that the Pelvic Mesh Products would be implanted in patients. When Defendants made these statements, Defendants knew or should have known that the statements were inaccurate.

47. Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

48. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the clearance process, labeling and other marketing activities that pertain to its Pelvic Mesh Products.

49. Defendants failed to perform or rely on proper and adequate testing and research in order to determine the safety and effectiveness of its Pelvic Mesh Products.

50. Defendants failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products; therefore, in the event of a failure, injury, or complication it is impossible to easily and safely remove Defendants' Pelvic Mesh Products.

51. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to Defendants' Pelvic Mesh Products.

52. Defendants' Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants.

53. The Pelvic Mesh Products implanted into Plaintiff JANICE FLANNAGAN were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by Defendants.

54. The injuries, conditions and complications suffered due to Defendants' Pelvic Mesh Products include but are not limited to mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to the woman's intimate partner.

55. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, Defendants have, and continue to manufacture, market and sell the Pelvic Mesh Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to Defendants' Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

56. Prior to the time that the Pelvic Mesh Products were implanted into Plaintiff JANICE FLANNAGAN, Defendants were aware of numerous defects in the Pelvic Mesh Products, including, but not limited to, the defects and unreasonable risks identified above. Based thereon, Defendants knew or should have known that the Pelvic Mesh Products caused an unreasonably high rate of complications, such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs in women implanted with the Pelvic Mesh Products. Despite being aware of the numerous defects and unreasonable risks in its products, Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products with the intent that it would be implanted in patients. Defendants were aware that implanting the Pelvic Mesh Products in patients was likely to cause injury and harm to the patients into whom the Pelvic Mesh Products were implanted. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

57. Even though Defendants have known or should have known that the Pelvic Mesh Products created a foreseeable, unreasonable risk of harm to those women into whom they were implanted, Defendants continued to market the Pelvic Mesh Products in the United States. Defendants have sold thousands of Pelvic Mesh Products in the United States alone.

58. Defendants have failed to provide adequate warning or information about the risks that the Pelvic Mesh Products cause an unreasonably high rate of complications, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs to physicians who implanted the Pelvic Mesh Products, or to women implanted with the Pelvic Mesh Products.

59. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. These complications included reports against AMS and Cook. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Cook and AMS are two of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

60. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

61. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported to the published scientific literature and in adverse event reports to the FDA. . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening, and vaginal pain."

62. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

63. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

64. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

65. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has not seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk."

66. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

67. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

68. At the time AMS and Cook began marketing their Pelvic Mesh Products, both Cook and AMS were aware that their respective Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

69. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to both Cook and AMS and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use or labeling.

70. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologist ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating that with regard to both AMS and Cook's Pelvic Mesh Products:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh. . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

71. The injuries of the female Plaintiff as will be more fully set forth in the Plaintiff's Profile Sheet and Fact Sheet to be served in this civil action are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

72. Cook knew or should have known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

73. AMS knew or should have known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

74. Cook knew or should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

75. AMS knew or should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

76. The scientific evidence shows that the material from which Cook's Pelvic Mesh Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products, including JANICE FLANNAGAN.

77. The scientific evidence shows that the material from which AMS' Pelvic Mesh Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products, including JANICE FLANNAGAN.

78. This negative response, from Cook's Pelvic Mesh Products as well as AMS' Pelvic Mesh Products, promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by JANICE FLANNAGAN.

79. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problems code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Cook Pelvic Mesh Products were unreasonably susceptible to degradation and fragmentation inside the body. The AMS Pelvic Mesh Products were unreasonably susceptible to degradation and fragmentation inside the body.

80. The Cook Pelvic Mesh Products were unreasonably susceptible to shrinkage and contraction inside the body. The AMS Pelvic Mesh Products were unreasonably susceptible to shrinkage and contraction inside the body.

81. The Cook Pelvic Mesh Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subjected to prolonged tension inside the body. The AMS Pelvic Mesh Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subjected to prolonged tension inside the body.

82. The Cook Pelvic Mesh Products have been and continue to be marketed to the medical community and patients to be safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

83. The AMS Pelvic Mesh Products have been and continue to be marketed to the medical community and patients to be safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

84. Defendant Cook omitted the risks, dangers, defects and disadvantages of their Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed their Pelvic Mesh Products as safe medical devices when Defendant Cook knew or should have known that the Pelvic Mesh Products were not safe for other intended purposes, and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, including JANICE FLANNAGAN, catastrophic injuries.

85. Defendant AMS omitted the risks, dangers, defects and disadvantages of their Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed their Pelvic Mesh Products as safe medical devices when Defendant AMS knew or should have known that the Pelvic Mesh Products were not safe for other intended purposes, and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, including JANICE FLANNAGAN, catastrophic injuries.

86. Contrary to Cook and AMS' representations and marketing to the medical community and to patients themselves, Cook and AMS' Pelvic Mesh Products have high rates of failure, injury and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions and damage to a significant number of women, including JANICE FLANNAGAN, making them defective under the law.

87. The specific nature of the Cook and AMS Pelvic Mesh Products' defects include, but is not limited to, the following:

a. AMS' use of polypropylene as well as AMS and Cook's use of collagen material and animal products in the Pelvic Mesh Products and the immune reactions that result from such material, cause adverse reactions and injuries;

b. the design of the polypropylene, collagen and animal product Pelvic Mesh Products to be inserted transvaginally, into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Cook and AMS Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. the inelasticity of the Cook and AMS Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

g. the propensity of the Cook and AMS Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen and biologic material lead to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen and biologic products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, as well as caused by biologic products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;

m. the design of trocars, as devices which as part of Cook and AMS' Pelvic Mesh Products and which are used to insert their Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve risk environments which results frequently in the destruction of nerve endings causing pain and other injuries.

88. The Cook and AMS Pelvic Mesh Products are also defective due to both AMS and Cook's failure to adequately warn or instruction JANICE FLANNAGAN and/or her health care providers of the subjects including, but not limited to, the following:

a. Cook and AMS' Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. Cook and AMS' Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. Cook and AMS' Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion and extrusion;

e. The risk of chronic inflammation resulting from Cook's Pelvic Mesh Products;

f. The risk of chronic inflammation resulting from AMS' Pelvic Mesh Products;

g. The risk of chronic infections resulting from Cook's Pelvic Mesh Products;

h. The risk of chronic infections resulting from AMS' Pelvic Mesh Products;

i. The risk of permanent vaginal or pelvic scarring as a result of Cook's Pelvic Mesh Products;

j. The risk of permanent vaginal or pelvic scarring as a result of AMS' Pelvic Mesh Products;

k. The irks of permanent vaginal shortening resulting from Cook's Pelvic Mesh Products;

l. The risk of permanent vaginal shortening resulting from AMS' Pelvic Mesh Products;

m. The risk of recurrent, intractable pelvic pain and other pain resulting from Cook's Pelvic Mesh Product;

n. The risk of recurrent, intractable pelvic pain and other pain resulting from AMS' Pelvic Mesh Product;

o. The need for corrective or revision surgery to repair or remove the Pelvic Mesh Product;

p. The severity of complications that could arise as a result of implantation of the Cook Pelvic Mesh Products;

q. The severity of complications that could arise as a result of implantation of the AMS Pelvic Mesh Products;

r. The hazards associated with the Cook Pelvic Mesh Products;

s. The hazards associated with the AMS Pelvic Mesh Products;

t. The Cook Pelvic Mesh Products' defects described herein;

u. The AMS Pelvic Mesh Products' defects described herein;

v. Treatment of pelvic organ prolapse and stress urinary incontinence with the Cook Pelvic Mesh Products is no more effective than feasible available alternatives;

w. Treatment of pelvic organ prolapse and stress urinary incontinence with the AMS Pelvic Mesh Products is no more effective than feasible available alternatives;

x. Treatment of pelvic organ prolapse and stress urinary incontinence with the Cook Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

y. Treatment of pelvic organ prolapse and stress urinary incontinence with the AMS Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

z. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

aa. Removal of the Pelvic Mesh Products due to complications, be the AMS product or Cook product, may involve multiple surgeries and may significantly impair the patient's quality of life;

bb. Complete removal of the Cook Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain; and

cc. Complete removal of the AMS Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

89. Defendant Cook has underreported information about the propensity of their Pelvic Mesh Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media. Cook has also underreported information about the injuries caused by the use of the implantation kits and surgical techniques instructions that accompany their pelvic meshes.

90. Defendant AMS has underreported information about the propensity of their Pelvic Mesh Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media. Cook has also underreported information about the injuries caused by the use of the implantation kits and surgical techniques instructions that accompany their pelvic meshes.

91. Defendant Cook failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

92. Defendant AMS failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

93. Defendants Cook failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

94. Defendants AMS failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

95. Feasible and suitable alternatives to the Cook and AMS Pelvic Mesh Products have existed at all time relevant that do not present the same frequency or severity of risks as do the Cook and AMS Pelvic Mesh Products.

96. The AMS Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to AMS, as AMS generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation and provided training for the implanting physician.

97. The Cook Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Cook, as Cook generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation and provided training for the implanting physician.

98. AMS provided incomplete and insufficient training and information to physicians regarding the use of their Pelvic Mesh Products and the aftercare of patients implanted with the AMS Pelvic Mesh Products.

99. The AMS Pelvic Mesh Products implanted into JANICE FLANNAGAN were in the same or substantially similar condition as they were when they left AMS's possession, and in the condition directed by and expected by AMS.

100. Cook provided incomplete and insufficient training and information to physicians regarding the use of their Pelvic Mesh Products and the aftercare of patients implanted with the Cook Pelvic Mesh Products.

101. The Cook Pelvic Mesh Products implanted into JANICE FLANNAGAN were in the same or substantially similar condition as they were when they left Cook's possession, and in the condition directed by and expected by Cook.

102. The medical and scientific literature studying the effects of AMS and Cook's Pelvic Mesh Products, like that of the Cook and AMS products implanted into JANICE FLANNAGAN, has examined the injuries, conditions and complications and has reported that they are causally related to the Pelvic Mesh Products.

103. At all relevant times herein, Cook continued to promote their Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

104. In doing so, Cook failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with their Pelvic Mesh Products.

105. At all relevant times herein, Cook failed to provide sufficient warnings and instructions that would have put JANICE FLANNAGAN and the general public on notice of the dangers and adverse effects caused by implantation of their Pelvic Mesh Products.

106. The Cook Pelvic Mesh Products as designed, manufactured, distributed, sold and/or supplied by Cook were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Cook's knowledge of lack of safety.

107. At all relevant times herein, AMS continued to promote their Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

108. In doing so, AMS failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with their Pelvic Mesh Products.

109. At all relevant times herein, AMS failed to provide sufficient warnings and instructions that would have put JANICE FLANNAGAN and the general public on notice of the dangers and adverse effects caused by implantation of their Pelvic Mesh Products.

110. The AMS Pelvic Mesh Products as designed, manufactured, distributed, sold and/or supplied by AMS were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of AMS' knowledge of lack of safety.

CASE-SPECIFIC ALLEGATIONS

111. On or about February 7, 2007, at Athens-Limestone Hospital, Plaintiff JANICE FLANNAGAN's physician implanted AMS' Pelvic Mesh Products, the Perigee System and Monarc sling, to treat a cystocele and stress urinary incontinence.

112. The AMS Products were implanted in Plaintiff JANICE FLANNAGAN to treat her stress urinary incontinence and cystocele, the use for which the Pelvic Mesh Products were designed, marketed and sold.

113. On or about June 16, 2011, at Athens-Limestone Hospital, Plaintiff JANICE FLANNAGAN's physician implanted Cook's Pelvic Mesh Products, that being Surgisis Biodesign Tension-Free Urethral Sling, to treat urinary incontinence.

114. The Cook Product was implanted in Plaintiff JANICE FLANNAGAN to treat her urinary incontinence the use for which the Product was designed, marketed and sold.

115. Prior to Plaintiff JANICE FLANNAGAN's surgery, her treating physician, as well as Plaintiff JANICE FLANNAGAN, was exposed to the aforementioned advertising and marketing campaign directed by Defendants AMS and Cook.

116. Plaintiff JANICE FLANNAGAN and her physician, either through direct promotional contact with Defendants' Sales Representatives, Lab Faculty, through word-of-mouth with other healthcare providers, and/or through promotional materials, received the information Defendants AMS and Cook intended Plaintiff JANICE FLANNAGAN and her physician to receive and view, to wit: that the Pelvic Mesh Products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

117. Plaintiff JANICE FLANNAGAN began experiencing excruciating and chronic pain, dyspareunia, vaginal bleeding, infections and urinary problems as well as the need for additional surgeries in June 2011 and November 2011.

118. Plaintiff JANICE FLANNAGAN began experiencing further excruciating and chronic pain, dyspareunia and urinary problems some time after the Cook Pelvic Mesh Product was implanted.

119. Plaintiff JANICE FLANNAGAN returned to her physicians several times due to complications and problems attributed to both AMS and Cook's Pelvic Mesh Products.

120. The medical and scientific literature studying the effects of Cook's Pelvic Mesh Products, like the Surgisis product implanted in JANICE FLANNAGAN, has examined each of the injuries, conditions and complications, like those of JANICE FLANNAGAN, and has reported that they are causally related to the Cook Pelvic Mesh Products.

121. The medical and scientific literature studying the effects of AMS' Pelvic Mesh Products, like the Sparc product implanted in JANICE FLANNAGAN, has examined each of the injuries, conditions and complications, like those of JANICE FLANNAGAN, and has reported that they are causally related to the AMS Pelvic Mesh Products.

122. As a direct and proximate result of the use of the Cook and AMS' Pelvic Mesh Products, Plaintiff JANICE FLANNAGAN suffered, and continues to suffer, serious bodily injury and harm. It was not until recently that Plaintiffs learned the Cook Pelvic Mesh Products were defective and the cause of JANICE FLANNAGAN's pain, suffering, and complications. It was not until recently that Plaintiffs learned the AMS Pelvic Mesh Products were defective and the cause of JANICE FLANNAGAN's pain, suffering, and complications.

123. As a direct and proximate result of the use of the Defendants Pelvic Mesh Products, Plaintiffs incurred, and continues to incur, medical expenses to treat JANICE FLANNAGAN's injuries and conditions.

124. As a direct and proximate result of the use of the Defendants Pelvic Mesh Products, Plaintiff JANICE FLANNAGAN continues to receive medical treatment and is anticipated to undergo further medical treatment.

COUNT I
AMS VIOLATED THE PRODUCT LIABILITY ACT –
DEFECTIVE MANUFACTURE AND DESIGN

125. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

126. One or more of the defects in the Pelvic Mesh Products are the result of improper or incorrect manufacturing processes that result in the Pelvic Mesh Products as manufactured deviating from their intended design. The defects caused by improper or incorrect manufacturing rendered the Pelvic Mesh Products unreasonably dangerous, deficient, and defective to consumers and to Plaintiff JANICE FLANNAGAN. The defects in the Pelvic Mesh Products implanted in Plaintiff JANICE FLANNAGAN existed from their manufacture; therefore the defects were present when they left the possession and control of AMS. The Pelvic Mesh Products were used by Plaintiffs in a reasonably foreseeable and intended manner.

127. AMS' Pelvic Mesh Products were "defective", unfit, unsafe, inherently dangerous and "unreasonably dangerous" for their intended and reasonably foreseeable uses. These Pelvic Mesh Products were in said condition when they entered the stream of commerce and were received by Plaintiffs. The Pelvic Mesh Products do not meet or perform to the expectations of patients and their healthcare providers. AMS' Pelvic Mesh Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

128. AMS' Pelvic Mesh Products create risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

129. AMS has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interest above the health and safety of the Plaintiffs and others.

130. AMS' Pelvic Mesh Product implanted into JANICE FLANNAGAN was not reasonably safe for its intended uses and were defective as described herein with respect to its design and manufacturing. As previously stated, the Pelvic Mesh Products' design defects include, but are not limited to:

a. The use of polypropylene material and/or collagen material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Products to be inserted into and through tan area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injury major nerve routs in the pelvic region;

e. The propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvic where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory response to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvic, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creating of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

131. The AMS Pelvic Mesh Products used by Plaintiff JANICE FLANNAGAN's physician were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Pelvic Mesh Products reached Plaintiffs in such a condition that was unreasonably dangerous to her. The AMS Pelvic Mesh Products were used in the manner for which they were intended, that is, for treatment of pelvic organ prolapse and/or stress urinary incontinence. This use resulted in injury to Plaintiffs.

132. At no time did Plaintiffs have reason to believe that Pelvic Mesh Products were in a condition not suitable for their proper and intended use among patients.

133. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defect of AMS' Pelvic Mesh Products. Further, in no way could Plaintiffs have known that AMS had manufactured the Pelvic Mesh Products in such a way as to increase the risk of harm or injury to the recipients of the implant.

134. AMS violated the common law in addition to Ala. Code § 6-5-500 et seq. and Ala. Code §§ 8-19-1 et seq.

135. As a direct and proximate result of AMS' wrongful conduct, including AMS' design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT II
COOK VIOLATED THE PRODUCT LIABILITY ACT
DEFECTIVE MANUFACTUREAND DESIGN

136. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

137. One or more of the defects in the Pelvic Mesh Products are the result of improper or incorrect manufacturing processes that result in the Pelvic Mesh Products as manufactured deviating from their intended design. The defects caused by improper or incorrect manufacturing rendered the Pelvic Mesh Products unreasonably dangerous, deficient, and defective to consumers and to Plaintiffs. The defects in the Pelvic Mesh Products implanted in Plaintiff JANICE FLANNAGAN existed from their manufacture; therefore the defects were present when they left the possession and control of Cook. The Pelvic Mesh Products were used by Plaintiffs in a reasonably foreseeable and intended manner.

138. Cook's Pelvic Mesh Products were "defective", unfit, unsafe, inherently dangerous and "unreasonably dangerous" for their intended and reasonably foreseeable uses. These Pelvic Mesh Products were in said condition when they entered the stream of commerce and were received by Plaintiffs. The Pelvic Mesh Products do not meet or perform to the expectations of patients and their healthcare providers. Cook' Pelvic Mesh Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

139. Cook's Pelvic Mesh Products create risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

140. Cook has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interest above the health and safety of the Plaintiffs and others.

141. The Cook's Pelvic Mesh Product implanted into JANICE FLANNAGAN was not reasonably safe for its intended uses and was defective as described herein with respect to its design and manufacturing. As previously stated, Cook's Pelvic Mesh Products' design defects include, but are not limited to:

a. The use of collagen material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injury major nerve routs in the pelvic region;

e. The propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvic where

they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory response to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvic, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creating of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

142. Cook's Pelvic Mesh Products used by Plaintiff JANICE FLANNAGAN's physician were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Pelvic Mesh Products reached Plaintiffs in such a condition that was unreasonably dangerous to her. The Cook Pelvic Mesh Products were used in the manner for which they were intended, that is, for treatment of pelvic organ prolapse and/or stress urinary incontinence. This use resulted in injury to Plaintiffs.

143. At no time did Plaintiffs have reason to believe that Cook Pelvic Mesh Products were in a condition not suitable for their proper and intended use among patients.

144. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defect of the Cook Pelvic Mesh Products. Further, in no way could Plaintiffs have known that Cook had manufactured the Pelvic Mesh Products in such a way as to increase the risk of harm or injury to the recipients of the implant.

145. Cook violated the common law in addition to Ala. Code § 6-5-500 et seq. and Ala. Code §§ 8-19-1 et seq.

146. As a direct and proximate result of Cook's wrongful conduct, including Cook's design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT III
AMS VIOLATED THE PRODUCT LIABILITY ACT - FAILURE TO WARN

147. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

148. AMS' Pelvic Mesh Products were defective by reason of failure of AMS to provide adequate warnings or instructions.

149. AMS failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers as to the proper candidates, if any, and the safest and most effective methods of implantation and use of AMS' Pelvic Mesh Products.

150. AMS failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers as to the risks and benefits of AMS' Pelvic Mesh Products, given the Plaintiffs condition and need for information.

151. AMS failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

152. AMS failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Pelvic Mesh

Products or to those women who had been implanted with the Pelvic Mesh Products, concerning the following risks, given their condition and need for information. AMS had actual or constructive knowledge of the following risks at the time the Pelvic Mesh Products left AMS' control and were being marketed:

a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Products;

f. The risk of chronic infections resulting from the Pelvic Mesh Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. The hazards associated with the Pelvic Mesh Products;

l. The Pelvic Mesh Products' defects described herein;

m. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Use of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

153. After receiving notice of numerous bodily injuries resulting from the Pelvic Mesh Products, AMS failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the Pelvic Mesh Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore AMS failed to provide post-marketing or post-sale warning instructions concerning the necessity to remove the Pelvic Mesh Products from the patient's body in the event of the product failure or other complications.

154. AMS intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the AMS Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiffs.

155. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

156. AMS are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the common law.

157. AMS violated the common law in addition to Ala. Code § 6-5-500 et seq. and Ala. Code §§ 8-19-1 et seq.

158. As a direct and proximate result of AMS' wrongful conduct, including AMS' wrongful design, manufacture, marketing, sale and distribution of the Pelvic Mesh Products, both at the time of marketing and after the sale of the Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT IV
COOK VIOLATED THE PRODUCT LIABILITY ACT - FAILURE TO WARN

159. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

160. Cook's Pelvic Mesh Products were defective by reason of failure of Cook to provide adequate warnings or instructions.

161. Cook failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers as to the proper candidates, if any, and the safest and most effective methods of implantation and use of Cook' Pelvic Mesh Products.

162. Cook failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers as to the risks and benefits of Cook's Pelvic Mesh Products, given the Plaintiffs condition and need for information.

163. Cook failed to properly and adequately warn and instruct Plaintiffs and their healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

164. Cook failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Pelvic Mesh Products or to those women who had been implanted with the Pelvic Mesh Products, concerning the following risks, given their condition and need for information. Cook had actual or constructive knowledge of the following risks at the time the Pelvic Mesh Products left Cook's control and were being marketed:

a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Products;

f. The risk of chronic infections resulting from the Pelvic Mesh Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. The hazards associated with the Pelvic Mesh Products;

l. The Pelvic Mesh Products' defects described herein;

m. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Use of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

165. After receiving notice of numerous bodily injuries resulting from the Pelvic Mesh Products, Cook failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the Pelvic Mesh Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore Cook failed to provide post-marketing or post-sale warning instructions concerning the necessity to remove the Pelvic Mesh Products from the patient's body in the event of the product failure or other complications.

166. Cook intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Cook Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiffs.

167. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

168. Cook is strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the common law.

169. Cook violated the common law in addition to Ala. Code § 6-5-500 et seq. and Ala. Code §§ 8-19-1 et seq.

170. As a direct and proximate result of Cook's wrongful conduct, including Cook's wrongful design, manufacture, marketing, sale and distribution of the Pelvic Mesh Products, both at the time of marketing and after the sale of the Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT V
AMS NEGLIGENCE

171. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

172. At all times relevant herein, AMS had a duty to exercise reasonable and ordinary care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products, including a duty to ensure that the Pelvic Mesh Products did not pose a significantly increased risk of bodily injury to its users.

173. AMS had a duty to exercise reasonable care in the advertising and sale of the Pelvic Mesh Products, including a duty to warn and instruct Plaintiffs and other consumers, of the dangers associated with the use of the Pelvic Mesh Products that were known or should have been known to AMS at the time of the sale of the Pelvic Mesh Products to Plaintiffs.

174. AMS had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

175. AMS knew or should have known Plaintiffs could foreseeably suffer injury as a result of AMS' failure to exercise ordinary care as described above.

176. AMS failed to warn the general public, including Plaintiffs, of the risk of serious harm.

177. AMS breached its duty to Plaintiffs by failing to exercise due care under the circumstances.

178. AMS failed to exercise ordinary and reasonable care in the development, design, testing, inspecting, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products. AMS was negligent in that it failed to provide adequate warnings and instructions to Plaintiffs and to their physician regarding the Pelvic Mesh Products. AMS further breached its duty of care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

179. The reasons that AMS' negligence caused the Pelvic Mesh Products to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene material and/or collagen material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvic where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. The propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory response to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvic, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creating of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

180. AMS also negligently failed to warn or instruct Plaintiffs and/or their health care providers of subjects including, but not limited to, the following:

a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from eh Pelvic Mesh Products;

f. The risk of chronic infections resulting from the Pelvic Mesh Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. The hazards associated with the Pelvic Mesh Products;

l. The Pelvic Mesh Products' defects described herein;

m. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Use of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

181. As a direct and proximate result of AMS' wrongful conduct, including AMS' negligent design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT VI
COOK NEGLIGENCE

182. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

183. At all times relevant herein, Cook had a duty to exercise reasonable and ordinary care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products, including a duty to ensure that the Pelvic Mesh Products did not pose a significantly increased risk of bodily injury to its users.

184. Cook had a duty to exercise reasonable care in the advertising and sale of the Pelvic Mesh Products, including a duty to warn and instruct Plaintiffs and other consumers, of the dangers associated with the use of the Pelvic Mesh Products that were known or should have been known to Cook at the time of the sale of the Pelvic Mesh Products to Plaintiffs.

185. Cook had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

186. Cook knew or should have known Plaintiffs could foreseeably suffer injury as a result of Cook' failure to exercise ordinary care as described above.

187. Cook failed to warn the general public, including Plaintiffs, of the risk of serious harm.

188. Cook breached its duty to Plaintiffs by failing to exercise due care under the circumstances.

189. Cook failed to exercise ordinary and reasonable care in the development, design, testing, inspecting, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products. Cook was negligent in that it failed to provide adequate warnings and instructions to Plaintiffs or to their physician regarding the Pelvic Mesh Products. Cook further breached its duty of care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

190. The reasons that Cook's negligence caused the Pelvic Mesh Products to be unreasonably dangerous and defective include, but are not limited to:

a. The use of collagen material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvic where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. The propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory response to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvic, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creating of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

191. Cook also negligently failed to warn or instruct Plaintiffs and/or their health care providers of subjects including, but not limited to, the following:

a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from eh Pelvic Mesh Products;

f. The risk of chronic infections resulting from the Pelvic Mesh Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. The hazards associated with the Pelvic Mesh Products;

l. The Pelvic Mesh Products' defects described herein;

m. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapsed and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Use of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

192. As a direct and proximate result of Cook's wrongful conduct, including Cook's negligent design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT VII
AMS BREACH OF EXPRESS WARRANTY

193. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

194. At all relevant and material times, AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all

activities that are part and parcel of the sale and distribution of its products, the Pelvic Mesh Products, representing the quality and effectiveness to healthcare professionals, the FDA, Plaintiffs and the public in such a way as to induce its purchase or use, thereby making an express warranty that the AMS Pelvic Mesh Products would conform to the representations. More specifically, AMS represented that the Pelvic Mesh Products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff JANICE FLANNAGAN, and/or that they were safe and effective to treat Plaintiff JANICE FLANNAGAN's conditions.

195. At all relevant times, AMS intended that the AMS Pelvic Mesh Products be used in the manner that Plaintiffs used and AMS expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal, and that it was adequately tested and fit for its intended use.

196. At all relevant times, AMS was aware that consumers, including Plaintiffs, would use the AMS Pelvic Mesh Products; which is to say that Plaintiff JANICE FLANNAGAN was a foreseeable user of the AMS Pelvic Mesh Products.

197. Plaintiffs and/or JANICE FLANNAGAN's implanting physicians were at all relevant times in privity with AMS.

198. The AMS Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs and JANICE FLANNAGAN's implanting physician, without substantial change in the condition in which they were manufactured and sold by AMS.

199. At all relevant times, Plaintiffs and/or JANICE FLANNAGAN's implanting physicians used the AMS Pelvic Mesh Products for the purpose and in the manner intended by AMS.

200. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good and become part of the basis of the bargain creating an express warranty that the good shall conform to the affirmations of fact or promises.

201. The AMS Pelvic Mesh Products did not conform to the representations made by AMS. AMS breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

a. AMS represented to Plaintiffs and JANICE FLANNAGAN's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the AMS Pelvic Mesh Products were safe and effective, when in reality AMS fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. AMS represented to Plaintiffs and JANICE FLANNAGAN's physicians and healthcare providers that the AMS Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information which demonstrated that the Pelvic Mesh Products were not safer than alternatives available on the market; and

c. AMS represented to Plaintiffs and JANICE FLANNAGAN's physicians and healthcare providers that the AMS Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the Pelvic Mesh Products.

202. In reliance upon AMS' express warranty, Plaintiff JANICE FLANNAGAN was implanted with the AMS Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted and marketed by AMS.

203. At the time of making such express warranties, AMS knew or should have known that the AMS Pelvic Mesh Products do not conform to these express representations because the AMS Pelvic Mesh Products were not safe and have numerous serious side effects, many of

which AMS did not accurately warn about, thus making the AMS Pelvic Mesh Products unreasonably unsafe for their intended purpose.

204. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the public, relied upon the representations and warranties of AMS in connection with the use recommendation, description, and/or dispensing of the AMS Pelvic Mesh Products.

205. Plaintiffs and JANICE FLANNAGAN's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

206. AMS breached its express warranties to Plaintiffs in that AMS' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

207. The Pelvic Mesh Products implanted in Plaintiff JANICE FLANNAGAN failed to function as intended and as represented by AMS because they did not relieve the symptoms or otherwise alleviate the medical problems they were intended to cure. Instead, the Pelvic Mesh Products caused Plaintiff JANICE FLANNAGAN to suffer severe and debilitating pain, dyspareunia, infections, bleeding, dyspareunia, bladder problems and other severe adverse health consequences. Because the Pelvic Mesh Products failed to conform to representations and were not suitable for the purpose for which they were used, AMS has breached its expressed warranties.

208. AMS violated the common law in addition to Ala. Code §§ 7-2-313, 7-2-314, et seq.

209. As a direct and proximate result of AMS' wrongful conduct, including AMS' breach of express warranty, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT VIII
COOK BREACH OF EXPRESS WARRANTY

210. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

211. At all relevant and material times, Cook developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of its product, the Pelvic Mesh Products, representing the quality and effectiveness to healthcare professionals, the FDA, Plaintiffs and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Cook Pelvic Mesh Products would conform to the representations. More specifically, Cook represented that the Pelvic Mesh Products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff JANICE FLANNAGAN, and/or that they were safe and effective to treat Plaintiff JANICE FLANNAGAN's conditions.

212. At all relevant times, Cook intended that the Cook Pelvic Mesh Products be used in the manner that Plaintiffs used and Cook expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal, and that it was adequately tested and fit for its intended use.

213. At all relevant times, Cook was aware that consumers, including Plaintiffs, would use the Cook Pelvic Mesh Products; which is to say that Plaintiff JANICE FLANNAGAN was a foreseeable user of the Cook Pelvic Mesh Products.

214. Plaintiffs and/or JANICE FLANNAGAN's implanting physicians were at all relevant times in privity with Cook.

215. The Cook Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs and JANICE FLANNAGAN's implanting physician, without substantial change in the condition in which they were manufactured and sold by Cook.

216. At all relevant times, Plaintiffs and/or JANICE FLANNAGAN's implanting physicians used the Cook Pelvic Mesh Products for the purpose and in the manner intended by Cook.

217. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good and become part of the basis of the bargain creating an express warranty that the good shall conform to the affirmations of fact or promises.

218. The Cook Pelvic Mesh Products did not conform to the representations made by Cook. Cook breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

a. Cook represented to Plaintiffs and/or JANICE FLANNAGAN's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Cook Pelvic Mesh Products were safe and effective, when in reality Cook fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. Cook represented to Plaintiffs and/or JANICE FLANNAGAN's physicians and healthcare providers that the Cook Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information which demonstrated that the Pelvic Mesh Products were not safer than alternatives available on the market; and

c. Cook represented to Plaintiffs and/or JANICE FLANNAGAN's physicians and healthcare providers that the Cook Pelvic Mesh Products

were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the Pelvic Mesh Products.

219. In reliance upon Cook's express warranty, Plaintiff JANICE FLANNAGAN was implanted with the Cook Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted and marketed by Cook.

220. At the time of making such express warranties, Cook knew or should have known that the Cook Pelvic Mesh Products do not conform to these express representations because the Cook Pelvic Mesh Products were not safe and have numerous serious side effects, many of which Cook did not accurately warn about, thus making the Cook Pelvic Mesh Products unreasonably unsafe for their intended purpose.

221. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the public, relied upon the representations and warranties of Cook in connection with the use recommendation, description, and/or dispensing of the Cook Pelvic Mesh Products.

222. Plaintiffs and JANICE FLANNAGAN's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

223. Cook breached its express warranties to Plaintiffs in that Cook' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

224. The Pelvic Mesh Products implanted in Plaintiff JANICE FLANNAGAN failed to function as intended and as represented by Cook because they did not relieve the symptoms or otherwise alleviate the medical problems they were intended to cure. Instead, the Pelvic Mesh Products caused Plaintiff JANICE FLANNAGAN to suffer severe and debilitating pain,

dyspareunia, infections, bleeding, bladder problems and other severe adverse health consequences. Because the Pelvic Mesh Products failed to conform to representations and were not suitable for the purpose for which they were used, Cook has breached its expressed warranties.

225. Cook violated the common law in addition to Ala. Code §§ 7-2-313, 7-2-314, et seq.

226. As a direct and proximate result of Cook's wrongful conduct, including Cook's breach of express warranty, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT IX
AMS BREACH OF IMPLIED WARRANTY

227. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

228. At all relevant and material times, AMS manufactured, distributed, advertised, promoted and sold AMS Pelvic Mesh Products.

229. At all relevant times, AMS intended that AMS Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiffs or JANICE FLANNAGAN's implanting physicians in fact used them and AMS impliedly warranted each product to be of merchantable quality, safe and fit for such use, and were not adequately tested.

230. AMS was aware that consumers, including Plaintiffs or JANICE FLANNAGAN's physicians, would implant AMS' Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff JANICE FLANNAGAN was a foreseeable user of AMS' Pelvic Mesh Products.

231. Plaintiffs and/or h JANICE FLANNAGAN's physicians were at all relevant times in privity with AMS.

232. The AMS Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs or Plaintiff JANICE FLANNAGAN' physicians, without substantial change in the condition in which AMS manufactured and sold their AMS Pelvic Mesh Products.

233. AMS breached various implied warranties with respect to the AMS Pelvic Mesh Products, including the following particulars:

a. AMS represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that AMS Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. AMS represented that AMS Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that AMS Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c. AMS represented that AMS Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy.

234. In reliance upon AMS' implied warranty, Plaintiffs used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by AMS.

235. AMS breached its implied warranty to Plaintiffs in that AMS Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles.

236. AMS violated the common law in addition to Ala. Code §§ 7-2-314, et seq.

237. As a direct and proximate result of AMS' wrongful conduct, including AMS' breach of implied warranty, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT X
COOK BREACH OF IMPLIED WARRANTY

238. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

239. At all relevant and material times, Cook manufactured, distributed, advertised, promoted and sold Cook Pelvic Mesh Products.

240. At all relevant times, Cook intended that Cook Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiffs or JANICE FLANNAGAN's implanting physicians in fact used them and Cook impliedly warranted each product to be of merchantable quality, safe and fit for such use, and were not adequately tested.

241. Cook was aware that consumers, including Plaintiffs or Plaintiff JANICE FLANNAGAN's physicians, would implant Cook's Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff JANICE FLANNAGAN was a foreseeable user of Cook's Pelvic Mesh Products.

242. Plaintiffs and/or JANICE FLANNAGAN's physicians were at all relevant times in privity with Cook.

243. The Cook Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs or JANICE FLANNAGAN's physicians, without substantial change in the condition in which Cook manufactured and sold its Cook Pelvic Mesh Products.

244. Cook breached various implied warranties with respect to the Cook Pelvic Mesh Products, including the following particulars:

a. Cook represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that Cook Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. Cook represented that Cook Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that Cook Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c. Cook represented that Cook Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy.

245. In reliance upon Cook's implied warranty, Plaintiffs used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Cook.

246. Cook breached its implied warranty to Plaintiffs in that Cook Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles.

247. Cook violated the common law in addition to Ala. Code §§ 7-2-314, et seq.

248. As a direct and proximate result of Cook's wrongful conduct, including Cook's breach of implied warranty, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XI
AMS COMMON LAW FRAUD

249. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

250. AMS has falsely and fraudulently represented and continue to represent to the Plaintiff, medical and healthcare community, the FDA and the public that Pelvic Mesh Products had been tested and were found to be safe and effective.

251. The representations made by AMS were, in fact, false. When AMS made their representations, AMS knew and/or had reason to know that those representations were false, and AMS willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

252. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. These complications included reports against AMS and Cook. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Cook and AMS are two of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

253. Despite the FDA's statement that complications caused by the mesh were "rare," AMS knew at all times material to these actions that complications were, in fact, not rare. Furthermore, the AMS knew at all relevant times that the FDA's focus on training and surgical technique of the implanting physicians was misguided.

254. At all time prior to the October 20, 2008 Public Health Notification to the present, it was known or knowable to AMS that its Pelvic Mesh Products caused large numbers of complications that were not rare. Moreover, it was known or knowable to AMS that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to AMS that the safety and efficacy of its Pelvic Mesh Products had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to AMS that there was no evidence that its Pelvic Mesh Products were safe and effective and, in fact, the evidence that was known or knowable to AMS was that its Pelvic Mesh Products were not safe and effective. AMS continued to represent that its Pelvic Mesh Products were safe and effective.

255. Despite what was known or knowable to AMS about the lack of safety and efficacy of its Pelvic Mesh Products prior to 2008, AMS failed to disclose this information to the plaintiff, to her physicians or to the public at large.

256. Despite this knowledge, AMS continued to market and sell its Pelvic Mesh Products and procedures as being safe and efficacious with evidence to the contrary. Additionally, AMS wrongfully and intentionally, through its physician training program, provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

257. These representations were made by AMS with the intent of defrauding and deceiving the medical and healthcare community, Plaintiffs and the public, and also inducing the medical and healthcare community, Plaintiffs and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary

incontinence and/or pelvic organ prolapse, all of which evinced a callous, reckless, willful and depraved indifference to the health, safety and welfare of Plaintiffs.

258. In representations to Plaintiffs and/or to Plaintiffs' healthcare providers, AMS fraudulently concealed and intentionally omitted the following material information:

a. That AMS' Pelvic Mesh Products were not as safe as other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

b. That the risk of adverse events with the AMS Pelvic Mesh Products was higher than with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

c. AMS' Pelvic Mesh Products were not adequately tested;

d. That the limited clinical testing revealed that AMS' Pelvic Mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

e. That AMS deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f. That AMS were aware of dangers in the AMS Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

g. That AMS' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

h. That patients needed to be monitored more regularly than usual while using the AMS Pelvic Mesh Products and that in the event the Pelvic Mesh Product needed to be removed that the procedures to remove then had a very high failure rate and/or needed to be performed repeatedly;

i. That the AMS Pelvic Mesh Products were manufactured negligently;

j. That the AMS Pelvic Mesh Products were manufactured defectively;

k. That the AMS Pelvic Mesh Products were designed negligently and designed defectively.

259. AMS was under a duty to disclose to Plaintiffs and JANICE FLANNAGAN's physicians, the defective nature of the AMS Pelvic Mesh Products, including, but not limited to, the heightened risks of mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs and other permanent injuries.

260. AMS had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used AMS' Pelvic Mesh Products.

261. AMS' concealment and omissions of material facts concerning the safety of the Pelvic Mesh products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the AMS Pelvic Mesh Products; and/or to mislead Plaintiffs into reliance and cause Plaintiff JANICE FLANNAGAN to use the AMS Pelvic Mesh Products.

262. At the time these representations were made by AMS, and at the time Plaintiff JANICE FLANNAGAN used AMS' Pelvic Mesh Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

263. AMS knew and had reason to know that the AMS Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of AMS' Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

264. In reliance upon these false representations, Plaintiffs were induced to, and did use AMS' Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. AMS knew or had reason to know that Plaintiffs and JANICE FLANNAGAN's physicians and other healthcare providers had no way to determine the truth behind AMS' concealment and omissions, and that these included material omissions of facts surrounding the use of the AMS Pelvic Mesh Products, as described in detail herein.

265. Plaintiffs reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the AMS Pelvic Mesh Products.

266. Having knowledge based upon AMS' research and testing, or lack thereof, AMS blatantly and intentionally distributed false information, including but not limited to assuring Plaintiffs, the public and JANICE FLANNAGAN's healthcare providers and physicians, that AMS' Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of AMS' research and testing, or lack thereof, AMS intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs and the public at large.

267. AMS had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiffs, JANICE FLANNAGAN's healthcare providers and physicians, and the United States Food and Drug Administration ("FDA").

268. The information distributed to the public, the medical and healthcare community, the FDA, and Plaintiffs, by AMS included, but was not limited to websites, information

presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the AMS Pelvic Mesh Products.

269. AMS intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the AMS Pelvic Mesh Products specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the AMS Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or pelvic organ prolapse.

270. AMS intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

271. AMS chose to over-promote the purported safety, efficacy and benefits of the AMS Pelvic Mesh Products instead.

272. AMS' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical and healthcare community, and Plaintiffs; to gain the confidence of the public, the medical and healthcare community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce the public, the medical and healthcare community, and Plaintiffs to request, recommend, prescribe, dispense, purchase and continue to use AMS' Pelvic Mesh Products.

273. AMS made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that AMS' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

274. These representations, and others made by AMS, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

275. These representations, and others made by AMS, were made with the intention of deceiving and defrauding the public, the medical and healthcare community, and Plaintiffs, and were made in order to induce Plaintiffs, and JANICE FLANNAGAN's healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use and request the AMS Pelvic Mesh Products and their healthcare professionals to dispense, recommend or prescribe the AMS Pelvic Mesh Products.

276. AMS willfully, maliciously, recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the AMS Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products know to be dangerous and defective, and/or not as safe as other alternatives.

277. AMS willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiffs, as well as JANICE FLANNAGAN's healthcare professionals, into a false sense of security, so that Plaintiffs and JANICE FLANNAGAN's healthcare providers would rely on AMS' representations, and Plaintiffs would request and purchase the AMS Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe and recommend the AMS Pelvic Mesh Products.

278. AMS utilized direct-to-consumer advertising to market, promote and advertise the AMS Pelvic Mesh Products.

279. AMS was in a superior position to know the true quality, safety and efficacy of the AMS' Pelvic Mesh Products. However, AMS knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing material AMS provided to the FDA, physicians and the general public. Furthermore, AMS fraudulently and affirmatively concealed the defective nature of the AMS' Pelvic Mesh Products from Plaintiffs.

280. At the time the representations were made, Plaintiffs and JANICE FLANNAGAN's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the AMS Pelvic Mesh products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover AMS' false representations, nor would Plaintiffs with reasonable diligence have discovered the true facts or AMS' misrepresentations.

281. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the AMS Pelvic Mesh Products, Plaintiffs would not have purchased, used or relied on AMS' Pelvic Mesh Products.

282. AMS' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiffs.

283. As a direct and proximate result of AMS' wrongful conduct, including AMS' fraud, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XII
COOK COMMON LAW FRAUD

284. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

285. Cook has falsely and fraudulently represented and continue to represent to the Plaintiff, medical and healthcare community, the FDA and the public that Pelvic Mesh Products had been tested and were found to be safe and effective.

286. The representations made by Cook were, in fact, false. When Cook made its representations, Cook knew and/or had reason to know that those representations were false, and Cook willfully, wantonly, and recklessly disregarded the inaccuracies in its representations and the dangers and health risks to users of the Pelvic Mesh Products.

287. On October 20, 2008, the FDA issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. These complications included reports against Cook and AMS. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Cook and AMS are two of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

288. Despite the FDA's statement that complications caused by the mesh were "rare," Cook knew at all times material to these actions that complications were, in fact, not rare. Furthermore, the Defendants knew at all relevant times that the FDA's focus on training and surgical technique of the implanting physicians was misguided.

289. At all times prior to the October 20, 2008 Public Health Notification to the present, it was known or knowable to Cook that its Pelvic Mesh Products caused large numbers

of complications that were not rare. Moreover, it was known or knowable to Cook that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Cook that the safety and efficacy of its Pelvic Mesh Products had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to Cook that there was no evidence that its Pelvic Mesh Products were safe and effective and, in fact, the evidence that was known or knowable to Cook was that its Pelvic Mesh Products were not safe and effective. Cook continued to represent that its Pelvic Mesh Products were safe and effective.

290. Despite what was known or knowable to Cook about the lack of safety and efficacy of its Pelvic Mesh Products prior to 2008, Cook failed to disclose this information to the plaintiff, to her physicians or to the public at large.

291. Despite this knowledge, Cook continued to market and sell its Pelvic Mesh Products and procedures as being safe and efficacious with evidence to the contrary. Additionally, Cook wrongfully and intentionally, through its physician training program, provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

292. These representations were made by Cook with the intent of defrauding and deceiving the medical and healthcare community, Plaintiffs and the public, and also inducing the medical and healthcare community, Plaintiffs and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced a callous, reckless, willful and depraved indifference to the health, safety and welfare of Plaintiffs.

293. In representations to Plaintiffs and/or to JANICE FLANNAGAN's healthcare providers, Cook fraudulently concealed and intentionally omitted the following material information:

a. That Cook' Pelvic Mesh Products were not as safe as other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

b. That the risk of adverse events with the Cook Pelvic Mesh Products was higher than with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

c. Cook' Pelvic Mesh Products were not adequately tested;

d. That the limited clinical testing revealed that Cook' Pelvic Mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

e. That Cook deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f. That Cook were aware of dangers in the Cook Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

g. That Cook' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

h. That patients needed to be monitored more regularly than usual while using the Cook Pelvic Mesh Products and that in the event the Pelvic Mesh Product needed to be removed that the procedures to remove then had a very high failure rate and/or needed to be performed repeatedly;

i. That the Cook Pelvic Mesh Products were manufactured negligently;

j. That the Cook Pelvic Mesh Products were manufactured defectively;

k. That the Cook Pelvic Mesh Products were designed negligently and designed defectively.

294. Cook was under a duty to disclose to Plaintiffs and JANICE FLANNAGAN's physicians, the defective nature of the Cook Pelvic Mesh Products, including, but not limited to, the heightened risks of mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs and other permanent injuries.

295. Cook had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used Cook's Pelvic Mesh Products.

296. Cook's concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Cook Pelvic Mesh Products; and/or to mislead Plaintiffs into reliance and cause Plaintiffs to use the Cook Pelvic Mesh Products.

297. At the time these representations were made by Cook, and at the time Plaintiff JANICE FLANNAGAN used Cook's Pelvic Mesh Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

298. Cook knew and had reason to know that the Cook Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of Cook's Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

299. In reliance upon these false representations, Plaintiffs were induced to, and did use Cook's Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Cook knew or had reason to know that Plaintiffs and JANICE FLANNAGAN's physicians and other healthcare providers had no way to determine the truth behind Cook's concealment and omissions, and that these included material omissions of facts surrounding the use of the Cook Pelvic Mesh Products, as described in detail herein.

300. Plaintiffs reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Cook Pelvic Mesh Products.

301. Having knowledge based upon Cook's research and testing, or lack thereof, Cook blatantly and intentionally distributed false information, including but not limited to assuring Plaintiffs, the public and Plaintiffs' healthcare providers and physicians, that Cook's Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Cook's research and testing, or lack thereof, Cook intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs and the public at large.

302. Cook had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiffs, JANICE FLANNAGAN's healthcare providers and physicians, and the United States Food and Drug Administration ("FDA").

303. The information distributed to the public, the medical and healthcare community, the FDA, and Plaintiffs, by Cook included, but was not limited to websites, information

presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Cook Pelvic Mesh Products.

304. Cook intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the Cook Pelvic Mesh Products specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Cook Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or pelvic organ prolapse.

305. Cook intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

306. Cook chose to over-promote the purported safety, efficacy and benefits of the Cook Pelvic Mesh Products instead.

307. Cook's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical and healthcare community, and Plaintiffs; to gain the confidence of the public, the medical and healthcare community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce the public, the medical and healthcare community, and Plaintiffs to request, recommend, prescribe, dispense, purchase and continue to use Cook's Pelvic Mesh Products.

308. Cook made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that Cook's Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

309. These representations, and others made by Cook, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

310. These representations, and others made by Cook, were made with the intention of deceiving and defrauding the public, the medical and healthcare community, and Plaintiffs, and were made in order to induce Plaintiffs, and JANICE FLANNAGAN's healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use and request the Cook Pelvic Mesh Products and their healthcare professionals to dispense, recommend or prescribe the Cook Pelvic Mesh Products.

311. Cook willfully, maliciously, recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Cook Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products know to be dangerous and defective, and/or not as safe as other alternatives.

312. Cook willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiffs, as well as her healthcare professionals, into a false sense of security, so that Plaintiffs and JANICE FLANNAGAN's healthcare providers would rely on Cook's representations, and Plaintiffs would request and purchase the Cook Pelvic Mesh Products, and that JANICE FLANNAGAN's healthcare providers would dispense, prescribe and recommend the Cook Pelvic Mesh Products.

313. Cook utilized direct-to-consumer advertising to market, promote and advertise the Cook Pelvic Mesh Products.

314. Cook was in a superior position to know the true quality, safety and efficacy of the Cook Pelvic Mesh Products. However, Cook knowingly made false claims about the safety and quality of the Cook's Pelvic Mesh Products in the documents and marketing material Cook provided to the FDA, physicians and the general public. Furthermore, Cook fraudulently and affirmatively concealed the defective nature of the Cooks Pelvic Mesh Products from Plaintiffs.

315. At the time the representations were made, Plaintiffs and JANICE FLANNAGAN's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Cook Pelvic Mesh Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover Cook's false representations, nor would Plaintiffs with reasonable diligence have discovered the true facts or Cook's misrepresentations.

316. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Cook Pelvic Mesh Products, Plaintiffs would not have purchased, used or relied on Cook's Pelvic Mesh Products.

317. Cook's wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiffs.

318. As a direct and proximate result of Cook's wrongful conduct, including Cook's fraud, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XIII
AMS CONSTRUCTIVE FRAUD

319. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

320. AMS is in a unique position of knowledge concerning the quality, safety and efficacy of AMS' Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or JANICE FLANNAGAN's physicians, and AMS thereby hold a position of superiority over Plaintiffs and JANICE FLANNAGAN's physicians.

321. Despite its unique and superior knowledge regarding the defective nature of AMS' Pelvic Mesh Products, AMS continue to suppress, conceal, omit and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent to the intended use of AMS' Pelvic Mesh Products, as compared to other products and forms of treatment.

322. For example, scientists in the study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

323. AMS has concealed and suppressed material information, including limited clinical testing, that would reveal that AMS' Pelvic Mesh Products had a higher risk of adverse events, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, AMS has misrepresented the safety and efficacy of the Products.

324. AMS' representations about safety and efficacy are false, and AMS knew the representations were false when made, or in the alternative made such representations recklessly without any knowledge of the truth and as a positive assertion. AMS made such false representations about safety and efficacy through its written materials and speakers, including

their advertisements, trainers, lab faculty, leave behinds, publications, regulatory submissions and other written and oral materials.

325. Upon information and belief, AMS' misrepresentations were designed, and made with the intention, to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the AMS Pelvic Mesh Products. Plaintiffs and the medical community have relied upon AMS' material misrepresentations.

326. AMS took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and the medical providers and engaged in constructive fraud in its relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on AMS' misrepresentations.

327. As a direct and proximate result of AMS' wrongful conduct, including AMS' constructive fraud, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XIV
COOK CONSTRUCTIVE FRAUD

328. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

329. Cook is in a unique position of knowledge concerning the quality, safety and efficacy of Cook's Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or JANICE FLANNAGAN's physicians, and Cook thereby hold a position of superiority over Plaintiffs and JANICE FLANNAGAN's physicians.

330. Despite its unique and superior knowledge regarding the defective nature of Cook's Pelvic Mesh Products, Cook continue to suppress, conceal, omit and/or misrepresent

information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent to the intended use of Cook's Pelvic Mesh Products, as compared to other products and forms of treatment.

331. For example, scientists in the study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early. Other medical literature is also contained herein cites the complication rates of biologic mesh materials as well.

332. Cook has concealed and suppressed material information, including limited clinical testing, that would reveal that Cook's Pelvic Mesh Products had a higher risk of adverse events, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Cook has misrepresented the safety and efficacy of the Products.

333. Cook's representations about safety and efficacy are false, and Cook knew the representations were false when made, or in the alternative made such representations recklessly without any knowledge of the truth and as a positive assertion. Cook made such false representations about safety and efficacy through its written materials and speakers, including their advertisements, trainers, lab faculty, leave behinds, publications, regulatory submissions and other written and oral materials.

334. Upon information and belief, Cook's misrepresentations were designed, and made with the intention, to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Cook Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Cook's material misrepresentations.

335. Cook took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and the medical providers and engaged in constructive fraud in its

relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on Cook's misrepresentations.

336. As a direct and proximate result of Cook's wrongful conduct, including Cook's constructive fraud, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XV
AMS NEGLIGENT MISREPRESENTATION

337. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

338. AMS, for profit companies, had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of urinary incontinence and pelvic organ prolapse. The representations made by AMS, in fact, were false.

339. AMS failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while AMS was involved in its development, design, manufacture, label, package, distribution, marketing, testing, supply, advertisement, selling, quality assurance, quality control and otherwise engaged in all activities that are part and parcel of the sale and distribution in interstate commerce, because AMS negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

340. AMS breached its duty in representing that AMS' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians and the medical and healthcare community.

341. As a foreseeable, direct and proximate result of the negligent misrepresentation of AMS as set forth herein, AMS knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, injuries to the woman's intimate partner and other severe and personal injuries, which are permanent and lasting in nature.

342. AMS took unconscionable advantage of its dominant position of knowledge with regard to Plaintiffs and the medical providers and engaged in negligent misrepresentations in its relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on AMS' misrepresentations.

343. As a direct and proximate result of AMS' wrongful conduct, including AMS' negligent misrepresentation, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XVI
COOK NEGLIGENT MISREPRESENTATION

344. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

345. Cook, for profit companies, had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of urinary incontinence and pelvic organ prolapse. The representations made by Cook, in fact, were false.

346. Cook failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while Cook was involved in development, design, manufacture, label, package, distribution, marketing, testing, supply, advertisement, selling, quality assurance, quality control and otherwise engaged in all activities that are part and parcel of the sale and distribution in interstate commerce, because Cook negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

347. Cook breached its duty in representing that Cook's Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians and the medical and healthcare community.

348. As a foreseeable, direct and proximate result of the negligent misrepresentation of Cook as set forth herein, Cook knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic

nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, injuries to the woman's intimate partner and other severe and personal injuries, which are permanent and lasting in nature.

349. Cook took unconscionable advantage of its dominant position of knowledge with regard to Plaintiff and the medical providers and engaged in negligent misrepresentations in its relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on Cook's misrepresentations.

350. As a direct and proximate result of Cook's wrongful conduct, including Cook's negligent misrepresentation, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XVII
AMS PUNITIVE DAMAGES

351. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

352. At all times relevant hereto, AMS knew or should have known that the AMS Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort

to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

353. At all times material hereto, AMS attempted to misrepresent and did misrepresent facts concerning the safety of the AMS Pelvic Mesh Products.

354. At the time AMS designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Pelvic Mesh Products and failed to adequately warn Plaintiffs of the dangerous and defective nature of the Pelvic Mesh Products and thereby caused Plaintiffs' injuries, AMS knew, or in the exercise of the appropriate degree of care should have known, that its conduct created an extreme degree of risk of serious injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiffs, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

355. AMS' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the AMS Pelvic Mesh Products.

356. At all times material hereto, AMS knew and recklessly disregarded the fact that the AMS Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products and/or procedures and/or treatments.

357. At all times material hereto, AMS knew and recklessly disregarded the fact that the AMS Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

358. At all times material hereto, AMS intentionally misstated and misrepresented data and continued to misrepresent data so as to minimize the risk of injuries caused by the AMS Pelvic Mesh Products.

359. Notwithstanding the foregoing, AMS continues to aggressively market the AMS Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there are safer alternatives.

360. AMS knew of the AMS Pelvic Mesh Products' defective and unreasonably dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell the AMS Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by the AMS Pelvic Mesh Products.

361. AMS continue to intentionally and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the serious side effects of the AMS Pelvic Mesh Products in order to ensure continued and increased sales.

362. AMS' intentional, reckless, and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the AMS Pelvic Mesh Products against their benefits.

363. As a direct and proximate result of AMS' wrongful conduct, including the acts and omissions listed above, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XVIII
COOK PUNITIVE DAMAGES

364. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

365. At all times relevant hereto, Cook knew or should have known that the Cook Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

366. At all times material hereto, Cook attempted to misrepresent and did misrepresent facts concerning the safety of the Cook Pelvic Mesh Products.

367. At the time Cook designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Pelvic Mesh Products and failed to adequately warn Plaintiffs of the dangerous and defective nature of the Pelvic Mesh Products and thereby caused Plaintiffs' injuries, Cook knew, or in the exercise of the appropriate degree of care should have known, that its conduct created an extreme degree of risk of serious injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiffs, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

368. Cook's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the Cook Pelvic Mesh Products.

369. At all times material hereto, Cook knew and recklessly disregarded the fact that the Cook Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products and/or procedures and/or treatments.

370. At all times material hereto, Cook knew and recklessly disregarded the fact that the Cook Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

371. At all times material hereto, Cook intentionally misstated and misrepresented data and continued to misrepresent data so as to minimize the risk of injuries caused by the Cook Pelvic Mesh Products.

372. Notwithstanding the foregoing, Cook continues to aggressively market the Cook Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there are safer alternatives.

373. Cook knew of the Cook Pelvic Mesh Products' defective and unreasonably dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell the Cook Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Cook Pelvic Mesh Products.

374. Cook continues to intentionally and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the serious side effects of the Cook Pelvic Mesh Products in order to ensure continued and increased sales.

375. Cook's intentional, reckless, and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the Cook Pelvic Mesh Products against their benefits.

376. As a direct and proximate result of Cook's wrongful conduct, including the acts and omissions listed above, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT XIX
COOK PUNITIVE DAMAGES

377. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

378. Plaintiff JEFFREY FLANNAGAN is the spouse of Plaintiff, JANICE FLANNAGAN, as a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff, JEFFREY FLANNAGAN has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily further expenses of a similar nature in the future.

379. As a direct and proximate result of the above-described injuries sustained by Plaintiff, JANICE FLANNAGAN, her husband, Plaintiff, JEFFREY FLANNAGAN has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

380. AS a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff, JEFFREY FLANNAGAN has suffered physical harm and injury as a result of the Defendants' product as well as other damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants American Medical Systems, Inc., American Medical Systems Holdings, Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., Endo Health Solutions Inc., Cook Biotech, Inc., Cook Medical, Inc., Cook, Inc. and Cook Group, Inc., jointly and severally, as follows:

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to totally compensate Plaintiffs for all of their injuries and damages, both past, present and future;

b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, lost income, loss of earning capacity, permanent disability, and pain and suffering;

c. Restitution and disgorgement of profits;

d. Punitive damages;

e. Attorneys' fees, expenses, and costs of this suit;

f. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

g. Such other relief, monetary or equitable, as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs specifically demand a trial by jury of all claims asserted in this Complaint.

Dated: February 14, 2013

Respectfully submitted,

By: */s/ David F. Miceli*

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